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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,289	09/07/2000	Kevin P Francis	9400-0006	1639
23419	7590	07/25/2003		
COOLEY GODWARD, LLP 3000 EL CAMINO REAL 5 PALO ALTO SQUARE PALO ALTO, CA 94306			EXAMINER	SLOBODYANSKY, ELIZABETH
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)	
09/657,289	FRANCIS ET AL.	
Examiner	Art Unit	
Elizabeth Slobodyansky	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 16 May 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-8,21,22,24-29,34-36,49,56,58,64 and 69-82 is/are pending in the application.
  - 4a) Of the above claim(s) 60 and 83-86 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5-8,21,22,24-28,34-36,49,56,58,64 and 69-82 is/are rejected.
- 7) Claim(s) 4 and 29 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____                                     |

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## **DETAILED ACTION**

The amendment filed May 16, 2003 amending claims 1, 21, 28, 69 and 79-82 and canceling claim 68 has been entered.

Claims 1-8, 21, 22, 24-29, 34-36, 49, 56, 58, 60, 64 and 69-86 are pending.

Claims 1-8, 21, 22, 24-29, 34-36, 49, 56, 58, 64 and 69-82 are under consideration. Claims 60 and 83-86 are withdrawn.

### ***Claim Objections***

Claims 74-76 are objected to because of the following informalities: "A bacterium" should be typed instead of "A bacteria". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-8, 21, 22, 24-28, 34-36, 49, 56, 58, 64 and 69-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 5-8, 21, 22, 24-28, 34-36, 49, 56, 58, 64 and 69-82 comprise polynucleotides encoding "*lux*" genes. The specification defines "*lux*" genes as "prokaryotic genes associated with luciferase and photon emission" (page 18, lines 22-23). Thus, a genus of any "*lux*" gene encompasses both naturally occurring in any prokaryote wherein the *lux* operon has any order of the genes and man made or mutated genes.

The specification teaches the *lux* operon of Gram-negative bacterium *Photorhabdus (Xenorhabdus) luminescens* wherein the genes in the naturally occurring *lux* operon are ordered *luxCDABE*. The specification and the art teach that eleven species in four Gram-negative genera are known (page 1, lines 10-13). The claims are not limited to the *lux* genes from Gram-negative bacteria homologous to *lux* genes from *Photorhabdus luminescens* wherein the genes in the naturally occurring *lux* operon are ordered *luxCDABE*. The specification does not contain any disclosure of the structure and function of DNA sequences that encode *lux* polypeptides from other prokaryotic organisms. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally and functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus, a DNA encoding *lux* gene products from *Photorhabdus luminescens*. Moreover, the specification fails to describe

any other representative species by any identifying characteristics or properties other than the "functionality" of encoding a *lux* polypeptide and fails to provide any structure: function correlation present in all members of the claimed genus. Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-8 and 25-27 recite "Sa1", "Sa2", "Sa3", "Sa4", "Sa5", "Sa6", "Sp1", "Sp5", "Sp6", "Sp9", "Sp16" and "Sp17". The metes and bounds of these terms are not defined in the specification. It is unclear which sequences other than SEQ ID NOs:15, 16, 17, 18, 19 and 20 are encompassed by the terms "Sa1", "Sa2", "Sa3", "Sa4", "Sa5" and "Sa6", respectively. Similarly, it is unclear which sequences other than SEQ ID NOs:21, 22, 23, 24, 25 and 26 are encompassed by the terms "Sp1", "Sp5", "Sp6", "Sp9", "Sp16" and "Sp17", respectively.

***Allowable Subject Matter***

Claims 4 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed May 16, 2003 have been fully considered but they are not persuasive.

Arguments regarding the 112, 1st paragraph, new matter rejection and the 103(a) rejection are moot in view of the amendment. The 112, 2nd paragraph, rejection is reworded to address Applicants arguments (Remarks, page 11). Its part related to the rejection of "mini-transposon" is withdrawn.

With regard to the written description rejection, Applicants argue that "The specification more than adequately describes both relevant, identifying structural (e.g., the order of the lux operons, the position of the gram-positive ribosome binding sites) and functional (e.g., encodes luciferase, transcription results in polycistronic RNA) characteristics of the expression vectors as set forth in pending claims 1-3, 5-8, 34-26, 49, 56, 58 and 64" (page 10). This is not persuasive because while the order of elements is described, the genes themselves are not. The genes are described by function only and not by structures. Applicants further argue that "The actual

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sequences of various *luxA*, *luxB* and *luc*-encoding sequences were well known. What was not known prior to Applicants' disclosure is that these sequences could be structured and organized in expression cassettes and shuttle vectors as claimed. It is evident that the specification more than adequately describes how to select known *lux* and *luc* sequences and how to organize these sequences with additional polynucleotides into the claimed expression cassettes" (page 10). This is not persuasive because while the actual sequences of various *luxA*, *luxB* may have been known, the claims are not directed to the specific sequences structurally homologous to them. Only a single species of each of these genes is described, a lux gene (A, B, C, D, E) from *Photorhabdus luminescens* wherein the genes in the naturally occurring *lux* operon are ordered *luxCDABE*. The claims do not contain any limitations as to how other members of the claimed genus relate to the *lux* genes from *Photorhabdus luminescens*.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

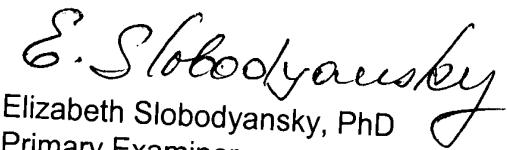
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

  
Elizabeth Slobodyansky, PhD  
Primary Examiner

July 23, 2003